

**REMARKS**

Favorable action on the merits is solicited in view of the following remarks.

The Examiner's attention is respectfully directed to the Appendix of this response, which includes two Declarations filed under 37 CFR 1.132, signed and dated October 14, 2009 and October 23, 2009. The declaration of October 14, 2009 declaration includes experimental results, and the declaration of October 23, 2009 provides an explanation of the various components in the claimed compositions. Both declarations are by Dr. Daniela Montanari, one of the named inventors of the present invention. Also included is the curriculum vitae (CV) of Dr. Daniela Montanari.

**Status of the Claims**

Claims 8-14 remain pending in this application.

**Claim Rejections-35 USC §112**

Claims 11-14 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that these claims (added in the amendment of May 30, 2008) contain new matter because they do not require hydroxyproline and aspartic acid to be complexed with a silanol.

However, the originally filed specification at page 4 beginning at line 20 states:

"However the original feature of the invention lies in its method of action and above all in the target of the action to combat hair loss, which is specifically the hair follicle. This action takes the following forms:

- it encourages elasticisation of the follicle walls in order to prevent them from hardening, thanks to the presence of two amino acids, hydroxyproline and aspartic acid, which maintain the function of the connective tissue structure surrounding and supporting the follicle,
- it helps to anchor the hair root in the follicle by holding it in its seat, delaying detachment and therefore loss thanks to the presence of an enzyme activator which acts on the transglutaminases." (Emphasis Added.)

That is, the original feature of the invention includes these two amino acids providing elasticity to the follicle walls.

Indeed, on page 5, line 8 of the specification it is noted that "[t]he two amino acids hydroxyproline and aspartic acid...have a cytostimulant effect".

The original specification further notes that the amino acids provide a particular action, e.g., beginning at Page 5, line 25:

"The inventors have considered it important to apply this action to the scalp by selecting monomethyl silanol-hydroxyproline aspartate as one of the active ingredients of the preparation according to the invention. As previously described, hair follicles are derived from an invagination in the skin and comprise an epidermal part and a connective tissue part in continuity with the dermis of the skin itself. This is the seat of action of the two amino acids, hydroxyproline and aspartic acid, which form part of the complex with the silanol." (Emphasis Added.)

Thus, the specification does disclose that these two amino acids, even without silanol, are effective in combating and/or delaying hair loss.

The activities of these amino acids are also explained in greater detail in declaration signed October 23, 2009.

Therefore, withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §103**

Claims 8-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over DESJONQUERES US 6,001,378 (DESJONQUERES) in view of HIRAMA et al. US 4,713,397 (HIRAMA) and ZAVERI et al. US 6,376,557(ZAVERI). This rejection is respectfully traversed.

DESJONQUERES was offered for teaching a composition for treating alopecia comprising organosilicone derivatives. However, DESJONQUERES fails to show any preference for monomethylsilanol-hydroxyproline aspartate recited in claim 8, as methylsilanol aspartate hydroxyprolinate is merely mentioned as an example of an organosilicone derivative. Indeed, neither the Examples, nor the claims mention the claimed active component.

Moreover, DESJONQUERES also fails to even recognize that hydroxyproline and aspartic acid, without the silanol complex as recited in independent claims 11 and 14, have an effect on decreasing hair loss.

HIRAMA was offered for teaching benzyl nicotinate for reducing hair fall out.

ZAVERI discloses treating alopecia using a commercially available mixture of octyl butyrate and glutamine-containing peptides.

The position of the Official Action was that it would have been obvious to combine the ingredients taught by these three documents to arrive at the claimed invention.

The proposed combination fails to disclose a preference for monomethylsilanol-hydroxyproline aspartate, as recited in independent claim 8, or even suggest the use of the combination of hydroxyproline and aspartic acid themselves, as recited in independent claims 11 and 14, in a composition for combating or delaying hair loss. Additionally, there is no suggestion of the superior results obtained by the claimed invention.

In the declaration signed and dated October 14, 2009, the results illustrate that the efficacy of the composition according to independent claim 8 (e.g., octyl butyrate glutamine peptides, monomethylsilanol-hydroxyproline aspartate, benzyl nicotinate, and panthenol) is superior to a composition of octyl butyrate and glutamine alone. For example, the claimed invention reduces hair loss in one third the time in half as many applications as that of a composition of octyl butyrate and glutamine alone. See, e.g., the table on page 7.

The declaration signed and dated October 23, 2009 explains the properties of the individual components, and that the aim of the claimed invention is to interfere with various mechanisms of hair loss without exerting any local pharmacological or systemic action.

With respect to independent claims 11 and 14 in particular, as evidenced by the discussion in the specification (e.g., page 4, lines 20-29 and page 5, lines 8-19 and 25-35) and the declaration signed and dated October 23, 2009, the combination of hydroxyproline and aspartic acid contribute to the anti-hair loss activity, which the proposed combination fails to suggest.

Therefore, as the proposed combination fails to suggest, at the very least, the unexpected superior results of the claims 8-10 and the composition described in claims 11-14, withdrawal of the rejection is respectfully requested.

**Conclusion**

In view of the declarations and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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**APPENDIX:**

The Appendix includes the following item(s):

- ☒ - a 37 CFR 1.132 Declaration by Dr. Daniela Montanari, which includes experimental data, dated October 14, 2009.
- ☒ - a 37 CFR 1.132 Declaration by Dr. Daniela Montanari, which includes a technical discussion of the active ingredients of the claimed invention, dated October 23, 2009.
- ☒ - The curriculum vitae (CV) of Dr. Daniela Montanari.